HRPO Protocol

1) Protocol Title (Version # and/or Version Date)

The Emotions and Decisions of Couples, #12-433, v. 06/13/2018

2) IRB Review History

N/A

3) Objectives

The proposed study is an experimental comparison of the effects of alcohol on arousal and emotion-regulation between 112 Distressed Violent (DV) and 112 Distressed Nonviolent (DNV) partners. One partner from each DV couple will be pseudo-randomly selected and yoked to a DNV partner of the same sex and a relationship satisfaction within a five-point range for participation in the experiment. To test the overall hypothesis that over-arousal is a mechanism through which alcohol is associated with increases in the frequency and severity of IPV, the selected partners will participate in a counter-balanced placebo session and alcohol administration session during which EEG, psychophysiology and pupillary response measurements of arousal will be collected during an emotion regulation task.

Specific Aim 1: To determine if normal increases in arousal after alcohol exposure is potentiated by evocative partner stimuli is greater for distressed violent (DV) partners compared to distressed nonviolent (DNV) partners. *Hypothesis 1a:* DV and DNV partners will experience comparable alcohol related increases in arousal. *Hypothesis 1b:* DV partners will demonstrate greater arousal increases by evocative partner displays than DNV partners. *Hypothesis 1c:* DV partners will experience greater arousal when exposed to alcohol and evocative partner stimuli than DNV partners.

Specific Aim 2: To determine if alcohol induced arousal interferes with DV partners' ability to regulate emotion in response to evocative partner stimuli compared to DNV partners. *Hypothesis 2a:* Emotion regulation during evocative stimuli will be reduced compared to neutral stimuli. *Hypothesis 2b:* Emotion regulation during evocative stimuli will be reduced by alcohol. *Hypothesis 2c:* DV partners will be less able to regulate emotion during evocative stimuli than DNV partners. *Hypothesis 2d:* Alcohol will interfere with DV partners' ability to regulate emotion during evocative stimuli compared to DNV partners.

4) Background

Intimate partner violence (IPV) is a significant public health problem that exacts a toll on medical and mental health care, social services and criminal justice systems. IPV is estimated to cost the United States $8.3 billion dollars annually. These costs include $6.2 billion for physical assaults, $460 million for rape, $461 million for stalking and $1.2 billion in the value of lost lives (Max, Rice, Finkelstein, Bardwell & Leadbetter, 2004). There are approximately 22.4 million physical assaults committed by a current or former intimate partner per year against an estimated 10 million Americans (Kessler, Molnar, Feurer & Appelbaum, 2001; Potter, Sacks, Kresnow & Mercy, 1999). National surveys reveal that nearly one third of couples will experience physical aggression at some point in their relationship and 16% of couples will experience IPV in any given year (Straus & Gelles, 1986). Furthermore, alcohol use is present in most instances of IPV

(57% to 70% of IPV incidents); during conflict, instances of physical aggression are more likely to occur than verbal aggression if one or both partners have used alcohol (Leonard & Quigley, 1999); and more severe IPV incidents occur during heavier drinking episodes (e.g., binge drinking; El-Bassel et al., 2004; Foran & O'Leary, 2008; Graham, Bernards, Wilsnack, & Gmel, 2011; Kantor & Straus, 1989; Pan, Neidig & O'Leary, 1994; Testa & Leonard, 2001). Relatedly, in a sample of newlywed couples, alcohol use led to more severe and more mutually violent episodes (Testa, Quigley & Leonard, 2003). In fact, in the 2013 New Mexico Intimate Partner Death Review Team Annual Report of Calendar Year 2010 found that 70 percent of perpetrators were under the influence of alcohol at the time of the murder and 25 percent of victims were consuming alcohol at the time of the incident (NMIPVDRT, 2013).

Despite the widespread financial, mental health, and physical consequences of IPV, we are woefully inadequate at effectively intervening with this problem, and currently, there are no effective interventions (Babcock, Green, & Robie, 2004; Sartin, Hansen & Huss, 2006). We argue that part of the field's inability to effectively intervene in or treat IPV is because we lack an integrated understanding of the constituent processes involved in IPV. There are two apparent elements of IPV, conflict induced arousal and alcohol use that, based on basic research of these processes, over-arousal would appear to negatively affect an individual's ability regulate one's emotions during highly aroused states. We argue that the best way to investigate the effect of these processes on incidents of IPV is to examine the neural, physiological and behavioral mechanisms of emotion-regulation during highly aroused states.

Behavior of Distressed Violent Couples and Arousal. Distressed violent (DV) couples engage in several unique dyadic and affective patterns that escalate conflict, physiological arousal, and distinguish them from distressed nonviolent (DNV) couples. DV couples are more likely to engage in *negative reciprocity,* which is the tendency to continue or escalate negative, and corrosive (evocative) behavior once it begins (Cordova, Jacobson, Gottman, Rushe & Cox, 1993). They also display abnormal *demand-withdraw patterns* (Babcock et al., 1993; Berns, Jacobson & Gottman, 1999; Christensen & Heavey, 1990). In a demand-withdraw pattern, individuals in a demanding role generally want more intimacy or closeness in an interaction and individuals in the withdrawing role generally want greater autonomy or separateness. In typical demand-withdraw patterns, one person of the dyad is usually in the demanding role and the other partner is in the withdrawing role (e.g., in divorcing couples). In DV couples, however, the partners alternate these roles, and all requests for closeness or intimacy (regardless of who is making them at the time) are met by withdrawal. This is a process that evokes chronic frustration and fear in the partners, and is a dynamic that lays the foundation for high conflict, power struggles, and clinging and hypervigilant responses (Babcock, Jacobson, Gottman & Yerington, 2000; Mikulincer, 1998).

DV couples also express higher levels of negative affect, such as contempt and belligerence, which escalate conflict beyond that seen in DNV couples (Gottman et al., 1995). Compared to DNV couples, DV couples become more psychologically abusive, emotionally aggressive and increasingly physiologically aroused as their conflict continues because of these patterns (Babcock et al., 1993; Frye & Karney, 2006; Gottman, et al., 1995; Jacobson, et al., 1994). Furthermore, verbal aggression and physical aggression are highly correlated in couples (Lundeberg, Stith, Penn & Ward, 2004) with 94% of those reporting physical aggression also

reporting verbal aggression (Shook, Gerrity, Jurich & Segrist, 2000). DV couples also have difficulty disengaging from conflict once it begins without escalating to physical aggression due in part to their highly aroused state (Ekman, 1984; Frye & Karney, 2006; Gottman, 1994; Jacobson, et al., 1994; Margolin, John & Foo, 1998; O'Leary, 1999). These findings suggest that DV couples are unable to regulate their emotional responses in the face of evocative conflict. Furthermore, partners in relationships whose conflict chronically generates such arousal become hypervigilant to potentially threatening and escalating interactions, and are more likely to misattribute threat potential to relatively neutral or positive acts (Gottman, 1994). These findings also suggest a sensitization process whereby repeated exposures to aversive dyadic interactions result in a progressive amplification of the arousal response to the partner's behavior.

Arousal and Aggression. Hostile aggression is widely conceptualized as being impulsive, anger driven, unplanned and occurring as a result of some sort of provocation or aggressive cue. Arousal is thought to influence aggression in some important ways. First, arousal can strengthen a dominant action tendency, meaning that if a person is instigated to aggress at the time arousal occurs, heightened aggression can result. Second, arousal can result from irrelevant sources (e.g., alcohol, exercise), thus producing anger-motivated aggressive behavior if the person is provoked. Thirdly, arousal is an aversive physiological state that motivates aggression the same way that other aversive stimuli, such as pain, do (Anderson & Bushman, 2002; Zillmann, 1983). Furthermore, laboratory examinations of arousal and hostile aggression show *over-arousal* is the state most likely to facilitate emotionally aggressive or violent acts (Scarpa & Raine, 1997) and that arousal will remain high when the provocation is perceived as being deliberate or intentional, much like the conflict of DV couples (Zillmann & Bryant, 1974; Zillmann & Cantor, 1976; Zillmann, Johnson, & Day, 1974; Zillmann, Katcher, & Milavsky, 1972). While IPV may appear on the surface to be higher towards females, this is likely due to a reporting bias rather than any real difference in the gender of the aggressor. In fact, meta-analytic studies of gender differences in aggressive behavior found that there are **no gender differences in aggressive behavior** when males and females are in aroused states (Knight, Guthrie, Page, & Fabes, 2002). This finding is consistent with the IPV literature of over 150 studies showing gender symmetry in IPV (Straus, 2006).

Alcohol's Effect on Neurophysiological and Psychophysiological Arousal. Low to moderate alcohol exposure has been shown to lead to neurophysiological and psychophysiological responses consistent with increased arousal. Although alcohol is considered a pharmacological depressant, during the absorption phase, also known as the ascending limb of intoxication, and at peak Blood Alcohol Concentration (BAC), alcohol is actually arousing (Levenson, Sher, Newman, & Newlin, 1980; Schwartz et al., 1981). Electroencephalography (EEG) investigations of EEG frequencies aligned with a continuum of consciousness have found that during the ascending limb of intoxication, and at peak Blood Alcohol Concentration (BAC), alcohol is associated with increases in fast frequencies (beta and alpha; alertness and vigilance, and wakefulness, respectively) and decreases in slow frequencies (theta and delta; drowsiness, and sleep, respectively; Sanz-Martin et al., 2011). This pattern of increases in fast frequencies and decreases in slow frequencies are traditionally associated with cortical arousal and an activated state (Andreassi, 2000; Coult, 1998; Matousek & Petersen, 1983; Neidermeyer, 1998;;

Schwarz et al., 1981) and has been considered to be an index of arousal in both animals and humans (Hernandez-Gonzales at al., 2008; Sanz-Martin et al., 2011).

Experimental administration of low to moderate alcohol (BAC up to .09g%) has also been shown to produce increases in pulse rates and finger pulse volumes, faster heart rate (HR), lower interbeat interval (i.e., lower heart rate variability), and higher skin conductance level (Burish, Maisto, & Shirley, 1982; Levenson, Sher, Grossman, Newman & Newlin, 1980). As with EEG, all of these psychophysiological changes with alcohol exposure are consistent with a physiologically aroused state (Burish, Maisto, & Shirley, 1982; Levenson, Sher, Grossman, Newman & Newlin, 1980). Similar to experimental studies of arousal and aggression, experimental studies of the conditions under which alcohol is related to aggression also find that alcohol is associated with aggressive behavior only under conditions of provocation and frustration (see Exum, 2006 for review). Furthermore, experimental manipulation of alcohol limb effects (i.e. ascending vs. descending limb) have provided evidence of increased aggressive tendencies on the ascending limb compared to the descending limb, thus providing further evidence of the role of alcohol induced arousal playing a potential role in IPV (Giancola & Zeichner, 1997).

In summary, the current application is investigating over-arousal as a mechanism through which alcohol is related to the increase in the frequency and severity of IPV. The experimental literature would suggest that the cortically and psychophysiologically arousing effects of alcohol during the ascending limb of intoxication and at peak BAC are compounded by the arousal created by DV couples' distinct conflict patterns leading to an increase in IPV. In addition, the literature suggests that DV couples' have difficulty regulating emotion in highly aroused states, and may be even less able to do so after alcohol use. This research will be used to inform the development novel interventions for IPV where, currently, no effective interventions exist.

5) Inclusion and Exclusion Criteria

Screening: Advertisements will invite interested couples to contact study staff for eligibility screening (for those without internet access) or direct participants to secure online eligibility screening via eSurvey. This service is provided by UNM to the PIs **at no cost**. Participants will provide informed consent for screening via either method. During screening, eligible couples will be informed of the video-taped couple interaction, asked to refrain from using illicit drugs or alcohol for at least 24 hours before each study sessions, and be required to provide a current state issued identification card (e.g. driver's license) to verify that they are at least 21 years of age at their initial session. Once eligibility criteria are assessed, participants will receive a full written informed consent document.

This study will recruit DV couples who experience violence only within the family. IPV of individuals also violent outside the family appears to be more related to their antisocial tendencies rather than the dyadic processes of family-only violent couples (Gottman et al., 1995). Because of this, participants will be screened for antisocial and generally violent behavior, and excluded from the study.

Participants: – Recruitment and screening will occur at the couple level. Participants will be a convenience sample of 112 DV couples and 112 DNV couples residing in the greater Albuquerque, NM metro area. Eligible couples will be 1) English-speaking, 2) heterosexual or homosexual, 3) between the ages of 21 and 45, and will provide informed consent. Because this is a study of the role of alcohol in IPV, all participants (DV & DNV) must 4) be in a distressed relationship (Revised Dyadic Adjustment Scale score below 47), 5) consume at least one to two alcoholic drinks per sitting each week for females and three to four alcoholic drinks for males, 6) report two binge drinking episodes (>4 drinks for males, >3 drinks for females) in month prior to assessment, 7) be married or cohabitating for at least six months, 8) both partners must be willing to participate, 9) must have a breath alcohol level of 0.0 g% at all visits. DV couples must have a history of at least mild physical aggression in the past six months (e.g.,twisted partner's arm or hair). Participants will be excluded if they are/have 1) currently separated, 2) an order of protection in place, 3) facing violence-related criminal charges, 4) currently in a domestic violence shelter, 5) evidence of psychosis or severe personality disturbance, 6) pregnant, 7) taking a medication contraindicated for use with alcohol, 8) currently taking insulin or oral hypoglycemic medication, 9) an AUDIT score greater than 19 indicating alcohol dependence, 10) illicit drug use (except marijuana), or 11) provide a positive UA at first emotion-regulation session. Participants will be screened for psychosis and severe personality disturbance using the SCID II psychosis and personality screeners. The age range reflects legal drinking age and age range used in other studies of alcohol and IPV (Eckhardt, 2007). The minimum length of relationship is to obtain a representative sample of DV couples. DV relationships are exceptionally unstable and dissolve at rates many times that of DNV relationships (Gortner et al., 1997). It is feared that older DV relationships may not be representative of DV relationships (e.g., less violent, Cui et al., 2013).

Adults unable to consent, individuals who are not yet adults, pregnant women and prisons will be excluded.

6) Number of Subjects (Recruitment Target)

Two hundred twenty-four (112 Distressed Violent and 112 Distressed NonViolent) couples will be enrolled in the study. We will screening 1200 couples in order to obtain the number to be enrolled in the study.

7) Recruitment Methods

Recruitment will be conducted using strategies discussed in Holtzworth-Munroe et al. (1992) for recruiting distressed violent couples (e.g., advertising for distressed couples) and will be conducted at the couple level. The Albuquerque, NM metropolitan area has a population of approximately 900,000, which is sufficiently large for the recruitment of a specialized sample. No recruitment will take place in domestic violence shelters, court mandated treatment settings, or through court referrals. Evidence suggests that individuals recruited from these locations are more likely to be generally violent (violence outside the family), have severe personality disturbances (antisocial personality

disorder), and have involvement in other criminal activity (1992). Participants will be recruited via advertisements placed throughout the Albuquerque Metro area, local newspapers, online forums, list serves, radio spots and television interviews. In addition, advertisements will be placed on ResearchMatch.org. Because of concerns about an invasion of privacy and the sensitivity of the data collected in this study, flyers will refer to generic aspects of relationship dissatisfaction and alcohol consumption.

In advertising for couples who drink alcohol weekly we have determined that this statement on the recruitment flyer or ad is selecting, almost exclusively, for individuals who have an alcohol use disorder or who are alcohol dependent, and therefore ineligible for our study. We are requesting permission to also place advertisements that do not include the "drink alcohol weekly" aspect of the inclusion criteria in the ad. The ad will continue to indicate that participants may consume alcohol during one or both experimental session, and we will continue screen for alcohol use consistent with our inclusion criteria (AUDIT score no greater than 19 and two binge episodes in previous month). (Please see the attached versions of the advertisement for the recruitment script and for how posted flyers will appear.)

Potential participants may endorse drinking levels making them ineligible for the study (AUDIT greater than 19). Such individuals will be given feedback regarding the drinking measures, and given referral information by the study staff or Dr. Fink. Following NIH guidelines, this referral will be an active referral. The staff member will present such individuals with a menu of options, provide a suggestion about a treatment option that is a good match, and will offer to call the facility and make an appointment for the individual.

8) Study Timelines

Participation in this study by participants will take a total of eight (8) hours over three sessions. Session one, the *Stimuli Acquisition Session*, will take two (2) hours and both partners of each couple will participate. Sessions two and three, the *Emotion-Regulation Sessions*, will be either a placebo or alcohol administration session. Participation in the placebo session will take one (1) hour. Participation in the alcohol administration session will take five (5) hours. The emotion-regulation and response inhibition tasks lasts approximately 30 minutes in each of the experimental sessions. The additional time in each session accounts for study set-up (attaching electrodes, etc.) and detoxification from alcohol in the alcohol-administration experimental session.

We anticipate enrolling study participants for two years and primary data analysis will be complete six months after the last participant is enrolled.

9) Study Endpoints

The study will be terminated if it is determined that the study procedures have resulted in a violent argument where physical aggression, including throwing or hitting the partner with an object that could inflict pain or injury, has occurred between three or more couples.

10) Research Setting

The UNM Clinical and Translational Science Center houses Dr. Fink's laboratory where the study will be conducted.

11) Study Methods

Screening: Advertisements will invite interested couples to contact study staff for eligibility screening (for those without internet access) or direct participants to secure online eligibility screening via REDCap. This service is provided by the CTSC to the PIs at no cost. Participants will provide informed consent for screening via either method. During screening, eligible couples will be informed of the video-taped couple interaction, asked not to use alcohol for at least 24 hours before their study sessions, and be required to provide a current state issued identification card (e.g. driver's license) to verify that they are at least 21 years of age at their initial session. Once eligibility criteria are assessed, participants will receive a full written informed consent document.

Couples who meet eligibility criteria for study inclusion will be invited to come to the UNM CTSC where they will receive detailed information about the study components and procedures, including the 15-minute discussion of a disagreement, and will have the opportunity to ask any questions that they have about participating. Participants will receive a full written informed consent document. The informed consent form will reiterate the experimental procedures, monetary compensation, risks and benefits, confidentiality of all data obtained, and the voluntary nature of all components of the study. The consent form will also ask the participants if their video segments may be used for training of research staff. In order for this to occur, both partners must provide permission and are free to retract this permission at any time without it affecting the rest of their study participation. The consent form will be approved Human Research Review Committee at the University of New Mexico prior to use. The PI, co-investigator or other research associate will be responsible for obtaining informed consent. The language used in the consent form will be easy to understand, participants will be reminded that they are free to not participate, or discontinue participation at any time during the study. If, however, it is during the alcohol adminsitration condition the participant must wait until their BAC is .03 or lower and participants must be not be displaying any angry affect greater than "feeling somewhat negative" prior to leaving the research site. Participants will also be informed that they are free to withdraw any information provided during the study, including erasing portions of the video recording. Should a participant make this request, it would result in the exclusion of the couple from further procedures and participation in the study as their video-taped communication discussion will be used at stimuli in subsequent study phases.

Note that participants who are deemed ineligible for participation will be given a list of area resources for assistance with relationship distress and/or partner violence, including procedures for filing for an order of protection. Participants will be required to bring a current state issued identification card (e.g. driver's license) to verify that they are at least 21 years of age. Furthermore, DV and DNV partners selected for participation in the *Emotion-Regulation Sessions* will receive instructions not to drive to their individual study sessions during their initial phone screen because of the possibility of receiving alcohol. This will be reiterated at the initial *Stimuli-Acquisition Session*. Participants will be required to have someone other than their partner (e.g., friend or family member) pick them up from the individual sessions. Alternatively,

participants will be provided with taxi vouchers if they need transportation back to their home address following detoxification. Female participants will provide a urine sample for a pregancy test before the alcohol administration condition and the placebo condition (to maintain blindness of participants to condition). The female partner will be excluded from the study if the test reveals she is pregnant.

***Stimuli Acquisition Session**:* Self-report instruments of relationship functioning, alcohol consumption, impulsivity, executive functioning and state/trait anger will be administered to both partners of each couple type (DV, DNV) separately. (Data from partners not selected for the emotion-regulation task will be preserved for future dyadic data analyses.) Partner stimuli for use in the emotion-regulation task will be acquired via the researcher facilitated Couple's Problem Inventory (CPI). The CPI ensures couples discuss an emotionally salient area of disagreement so that the laboratory discussion will mirror discussions at home to the degree possible in a laboratory setting. It is important to note the purpose of the researcher facilitated CPI interview is to ensure the couple discusses an emotionally salient area of disagreement so that the laboratory discussion will mirror such discussions at home to the degree possible in a laboratory setting. Any emotional carry-over from the self-report measures will only facilitate this process. Partners will be directed to discuss the topic and attempt to reach a resolution.

Stimuli Acquisition: Video cameras will be focused on the face of each partner to capture the content of the partner's speech as well as the partner's facial expressions during the discussion of a disagreement using two Canon VIXIA HF R400 video cameras. To ensure that there are not experimenter-introduced differences in the evocative stimuli used between groups in the subsequent experimental sessions, and to ensure we choose sufficiently arousing partner displays, stimuli selected will be according to the hierarchy of the Specific Affect (SPAFF) coding system (e.g., contempt, belligerence, criticism, defensiveness, stonewalling, respectively). It is important to note that conflict intensity differences likely naturally exist between DV couples and DNV couples (see Significance). Our method will ensure, however, that there are no experimenter introduced differences in the stimuli selected. Inter-rater reliabilities will be calculated on 50% of the videos and coders retrained to criterion if necessary. DV couples display at least 192 evocative behaviors per 15-minute disagreement discussion,[67] and partners are roughly equivalent in such displays[18] ensuring ample evocative stimuli for subsequent sessions. Displays of these evocative behaviors also distinguish DNV from satisfied couples.[40] Partners will be excluded from the remainder of the study should the couple fail to provide sufficient stimuli. If the couple is symmetrical in violent behavior, one partner will be randomly selected to participate in the remaining sessions. If the couple is asymmetrical, the most violent partner will be selected for participation. DV partners will be matched and yoked to a DNV partner of comparable distress.

***Emotion-Regulation Sessions**:* The selected partners (DV, DNV) will return to the laboratory on two separate occasions for the completion of the emotion-regulation sessions of the study. Once participants are prepped for biopotential recording, they will be administered either an alcohol beverage or placebo beverage (counter-balanced alcohol and placebo conditions; see below for procedures).

Alcohol Condition Protocol - Participants will receive a mixed drink (juice and 100-proof vodka) intended to raise their blood alcohol concentration (BAC) to a target dose of 0.08g% using a standard formula for calibrating the alcohol doses to achieve the target BACs.[68]

Specifically: Alcohol dose (g) = ((10 * BAC * TBW)/0.8) + (10 * MR * (DDP + TPB)) * (TBW/0.8). Participants will be asked to drink the beverage within 10 minutes to ensure that they remain on the ascending limb or reach peak BAC during the 25-minute experimental task. After completion of the experimental task, participants will continue to be breathalyzed every 15 minutes and when their BAC is less than 30 mg/dl (.03%), they will be excused.

Placebo Condition Protocol - Procedures will be identical to the alcohol condition, except participants will consume a volume of juice equivalent to that consumed in the alcohol condition with a small amount (~3 ml) of alcohol floated on top of the juice and misted with vodka to produce the taste and smell of alcohol. Participants will then complete the emotion-regulation task while biopotential data are collected.

EEG, Psychophysiology and Pupillary Response Acquisition - EEG and psychophysiology data will be collected using the BrainVision actiCHamp 64-channel, DC amplifier, 24-bit resolution, biopotential system. EEG data will be recorded with filters set at 1 and 30Hz, digitized at a sampling rate of 512Hz and stored on a computer using the PyCorder software. EEG data will be recorded to collect a 5-minute baseline measurement prior to administration of alcohol or placebo beverage. After beverage administration data will be collected for the duration of the emotion-regulation task (see below). To reduce confounding results due to artifacts, EEG signals will be examined for contamination by muscle activity and eye movement. Fast Fourier Transformation (FFT) analysis will be applied to 6-10 second epoch samples (corresponding to the delivery of stimuli) allowing for 1-s pre- and post-stimuli artifact subtraction with the spectral graph ranging from 0 to 30Hz at 0.5Hz-resolution. FFTs will be performed using EEGLab software to calculate 1) Absolute power (AP; power density of each frequency band expressed in microvolts squared; mV^2/Hz); 2) Relative power (RP; proportional contribution of each band to the total power across 1 – 30Hz). AP and RP will be transformed into Fisher's z-scores for statistical analyses. Skin conductance (SC) will be collected using the BrainVision GSR module with leads placed on the left index finger and left middle finger. SC will be recorded to collect a 5-minute baseline (as with EEG) measurement and for the duration of the emotion-regulation task and time-locked to evocative stimuli. SC data will be subjected to detrending and transformed to Fisher's z-scores for statistical analysis. Respiration and HRV will be measured using an integrated BrainVision respiration belt, and an EKG in Lead II position. As with EEG, baseline measures will be collected, and time locked to evocative events. EKG data will be quantified as respiratory sinus arrhythmia (RSA) which is a unique measure of parasympathetic activity and self-regulatory ability. Respiration and HRV data will also be transformed to Fisher's z-scores for statistical analysis. Pupillary response data will be collected using the EyeLink 1000 system high speed camera by SR Research (see sample data). Corneal reflection will be recorded at 250 Hz. The left and right pupil diameter measures will be averaged offline and baseline measures (1 sec prior to trial onset) will be subtracted. The difference between the maximum diameter during the trial and the baseline diameter will be calculated and transformed to Fisher's z-scores for statistical analysis. E-prime will control the flow of the emotion regulation task and generate timestamps to denote conditions for which all biopotential data can be analyzed.

Emotion Regulation Task -The proposed approach for studying emotion regulation has been used in several previous studies,[69] but we will utilize participant-tailored stimuli (video clips of partner's evocative behavior). During viewing, participants will be instructed to 1) experience the emotion they associate with the video (WATCH), or 2) to suppress the feeling of emotion (DON'T REACT). In the WATCH condition, participants will be instructed to let their

emotional experience occur naturally, and to pay attention to how they feel during the clip. In the DON'T REACT condition, participants will be instructed to attempt to suppress any feelings of emotion so as to prevent an observer watching physiological recordings from knowing that an emotional response has occurred. In both conditions, participants will be asked to indicate their corresponding emotional state using a slider (clicking and dragging with a mouse) on a continuous rating scale anchored by "very negative" (1) and "very positive" (100). A total of 50 unique video clips between 4 and 8 seconds in length will be used in the task; 25 evocative and 25 neutral. Each stimulus will be presented twice: once in the WATCH condition and once in the DON'T REACT condition. On each trial, participants will view a blank screen (1 second), fixation cross (1.5 sec), blank screen (.5 sec), the instruction (WATCH or DON'T REACT; 1.5 sec), the video clip (4-8 sec), and a blank screen (up to 2.5 seconds). The total amount of time required for the task will be approximately 25 minutes. Ratings obtained during the emotion regulation task will be averaged across stimulus type and regulation condition for the placebo and alcohol sessions for statistical analysis.

Participant Remuneration: Each participant will be paid $20 per hour for their participation in the study. Eachpartner will have the opportunity to earn $40 for his/her participation in the *Stimuli Acquisition Session* ($80 total). The partner invited back for the *Emotion-Regulation Sessions* will have the to earn $100 for his/her participation in the *Alcohol beverage Emotion-Regulation Session* and $20 in the *Placebo beverage Emotion-Regulation Sessions* for a total of $200 per couple. Participants will receive remuniration in the form of Visa or similar gift cards.

12) List of Appendices

Scale Purpose	Scale Name	Use/Source	α	Population
Screening	SCID-I & II Psychosis & Personality Screener	Identification & exclusion of psychosis & antisocial personality disorder;[55]	.75	Non-patients
	Revised Dyadic Adjustment Scale	Screening relationship satisfaction scale;[56]	.90	Couples
	Alcohol Use Disorders Identification Test	Identification & exclusion of problem drinking; [57]	.80	Individuals who drink alcohol
Demographic Data	Project Demographic Form	Demographic Data; project developed	N/A	Couples
Stimuli Acquisition	Couple's Problem Inventory	Scale to identify clear, current & emotionally salient area to discuss; obtain conflict intensity as covariate;[58]	N/A	Couples
	Discussion of Area of On-going Disagreement	Task where couples discuss area of disagreement for individual session stimuli acquisition.	N/A	Couples
	Specific Affect Coding System	Used to code conflict communication; SPAFF; [59]	N/A	Couples
Relationship Functioning / Conflict Processes	Dyadic Adjustment Scale	Relationship satisfaction scale;[60]	.96	Couples
	Conflict Tactics Scale-2	Measure of spectrum of conflict resolution behaviors including physical aggression;[61]	.95	Couples
	Communication Patterns Questionnaire	Demand-withdraw pattern questionnaire;[62]	.80	Couples
	Timeline Follow-back Interview	Calendar assessment of IPV in past 6 mos (this project)	N/A	Couples

(0.05)

	Flooding Quest.	Assesses tendency to become physiologically over-aroused during partner conflict	.88	Couples
Alcohol Consumption	Timeline Follow-back Interview	Calendar assessment of drinking in past 6 mos. (this project);[63]	.86	Individuals who drink alcohol
	Subjective High Assessment Scale	Assess subjective feelings of alcohol intoxication; SHAS;[64]	.96	Individuals who drink alcohol
	Self-Report of Effects of Alcohol Quest.	Assess self-reported sensitivity to alcohol.	N/A	Individuals who drink alcohol
	Alcohol Sensitivity Questionnaire	Assesses symptoms associated with ascending and descending limbs of intoxication	N/A	Individuals who drink alcohol
Individual Variables	UPPS-P Impulsive Behavior Scale	Assess impulsivity moderation of alcohol & IPV; used to obtain impulsivity as covariate;[65]	.91	Adult non-patients
	State Trait Anger Expression Inventory-2	Anger expression-out & anger expression-in for anger as emotional state & trait.	.82	Adult non-patients
	Behavior Rating Inventory of Executive Function-Adult Version	Self-report measure of executive functions as covariate;[66]	.93	Neurologically intact and diseased adults

Experimental Tasks:

Plain Vanilla Task - The Plain Vanilla Task is a physiologically non-demanding task used to collect resting heart-rate variability data. In this task, the participant simply watches a computer screen for five minutes while it changes colors and reports how many times the screen turned blue. While the participant is watching the screen psychophysiological measurements of heart rate variability are collected. This task will only be completed during one individual session before any alcohol is consumed.

Emotion-Regulation Task – The approach for studying emotion regulation described below has been used in several previous studies of emotion regulation (e.g. Dan-Glauser & Gross, 2011). While this approach has used pictures from standardized stimulus sets, the methods from these studies will guide the current design.

Participants will view a video comprised of their partner's contemptuous, belligerent, critical, defensive, stonewalling and neutral behavior from the previous couple session. During this time physiological measurements will be collected including galvanic skin response (GSR), heart rate, respiration, and heart rate variability (inter-beat interval). Baseline measures will be taken where the participant sits quietly for five minutes.

While viewing the video clips, participants will be given instructions to 1) experience the emotion they associated with the video (WATCH), or 2) to suppress the feeling of emotion (DON'T REACT). In the WATCH condition, participants will be shown video clips and are instructed to let emotional experience to occur naturally, and to pay attention to how they feel during the clip. In addition, participants are instructed to record their feelings using a continuous visual analogue scale. In the DON'T REACT condition, participants are instructed to attempt to suppress any feelings of emotion so as to prevent an observer watching physiological recordings from knowing that an emotional response has occurred.

A total of 50 unique video clips will be used in the task, 25 negative and 25 neutral. These video clips will be between 4 and 8 seconds in length and will be determined by the PI using the standardized *Specific Affect Coding System*. Each stimulus will be presented twice: once in the WATCH condition and once in the DON'T REACT condition.

On each trial, participants will view a blank screen (1 second), fixation cross (1.5 sec), blank screen (.5 sec), the instruction (WATCH or DON'T REACT; 1.5 sec), the video clip (4-8 sec), and a blank screen (up to 2.5 seconds). In addition, during the video presentation, a continous rating scale with the anchors very negative and very positive will be presented, and participants will be asked to indicate with a slider on the scale (by clicking and dragging with a mouse) how they currently feel. The scale slider will be set to the middle of the screen before each trial begins. The total amount of time required for the task will be approximately 25 minutes.

Response Inhibition Task – To measure response inhibition, we will use a variant of the stop signal task (Aron & Poldrack, 2006), which relies on estimating the time it takes an individual to engage inhibitory processes to overcome a prepotent response tendency. The stop signal task and other response inhibition tasks have been used in several previous studies of alcohol-induced disinhibition, with heavy drinkers showing enhanced stop times and enhanced inhibition errors after consumption of alcohol at a variety of alcohol doses. During the task, participants are presented arrows that point to the left (<) or to the right (>), and must make speeded responses indicating a left or right pointing arrow. However, on some trials, a tone is presented, signaling that participants should withhold their response. The task automatically adjusts the timing of the tone in order obtain approximately 50% correct responses (i.e. non-responses). The total time required for the task is 15 minutes.

13) Data and Specimen Banking **N/A**

14) Data Management

Questionnaire Data - Documents pertaining to demographic information, tactics used in conflict resolution between the partners, relationship satisfaction and stability, and alcohol sensitivity and consumption will be collected electronically via REDCap and saved on secure servers housed at the CTSC. (Please see above table for a description of the questionnaire data.) Before collection, questionnaire data will be identified by participant numeric code and saved on secure serves. The benefit of electronic data collection is two-fold. First, the immediate de-identification of the data allows it to be retained after the completion of the study. Second, it is in data base form and does not require data entry.

Psychophysiological Data - Psychophysiological data will initially be collected using laboratory computers. After each participant completes a laboratory procedure, the collected data will be transferred and saved to secure servers housed at the CTSC. Access to the servers is password protected and only authorized study personnel will be granted access.

Video Data - We request continued permission to keep the digital copies of the videos indefinitely because they contain significant clinical information that pertains to partner violence and because of that, impart significant scientific value. Blurring, distorting or destroying these videos would prevent us from accomplishing these goals and those of the current study. To ensure that the participant can make a fully informed consent regarding this, the consent form clearly states that the videotapes a) will show the participant's faces, b) will be kept indefinitely, and c) can and will be destroyed if the participant expressly requests that this be the case, which

is completely within their right. The digital videos will be delinked from identifying information, as described above. We understand that there is some question as to whether the videotapes themselves contain identifying information. Thus, increased caution must be imposed on the storage of these data. To this end, we will store the video data only in electronic form, on a different secured server than the rest of the study data, to prevent the implications of a potential server breach.

A master list of participant information and participant ID codes will be kept on a password protected computer in a locked room separate from any data collection computers (CTSC, Suite 3145, G). The purpose of this is to be able to contact participants and schedule them for their subsequent study visits. This list will be destroyed at the conclusion of data collection for this study.

Data Analysis Plan: Preliminary analyses will be performed to ensure no violation of the assumptions of normality, linearity and homoscedasticity. Appropriate transformations (e.g. log transform of positively skewed data) will be performed prior to data analysis. Data will be analyzed according to the aims of the study.

Specific Aim 1: To determine if normal increases in arousal after alcohol exposure is potentiated by evocative partner stimuli and is greater for DV partners compared to DNV partners. We will conduct a 2 (beverage condition: alcohol vs. placebo) x 2 (stimulus: evocative vs. neutral) repeated measures ANOVA with a between-subjects factor (partner type: DV vs. DNV). To test whether alcohol increases overall arousal (**Hypothesis 1a**), we will examine the main effect of alcohol vs. placebo on arousal variables, collapsing across partners and stimuli during the WATCH condition as alcohol should effect the arousal of both partner types equally. To test whether DV partners are more aroused by evocative partner displays than DNV partners (**Hypothesis 1b**), we will test the interaction effect of partner type and stimulus type, collapsing across alcohol and placebo conditions. Finally, to test the hypothesis that alcohol induced increases in arousal above placebo will be greater for evocative than neutral stimuli (**Hypothesis 1c**) for DV vs. DNV partners, we will test the three-way interaction in the 2 (DV vs. DNV) x 2 (alcohol vs. placebo) x 2 (evocative vs. neutral) repeated measures ANOVA. Specifically, this contrast will examine the effect of partner type when comparing stimuli type (evocative) to beverage condition (alcohol) on arousal and provides a critical control given that conflict intensity may differ between DV and DNV couples. The 3-way interaction (Hyp1c) will allow us to be able to determine whether the change in arousal between alcohol and placebo sessions for the evocative stimuli differs between couple types. The arousal level of evocative stimuli is matched between alcohol and placebo sessions, thus allowing for a controlled examination of alcohol-induced increases in arousal for evocative stimuli across DV and DNV couples.

Specific Aim 2: To determine if alcohol induced arousal interferes with DV partners' ability to regulate emotion in response to evocative partner stimuli compared to DNV partners. All hypotheses will be tested using a 2 (beverage condition: alcohol vs. placebo) x 2 (stimulus: evocative vs. neutral) x 2 (regulation condition: WATCH vs. DON'T REACT) repeated measures ANOVA with a between-subjects factor (partner type: DV vs. DNV). Testing specific interactions within the overall model will test each hypothesis. If the ages of the DV and DNV partners are significantly different, ANCOVAs will be conducted as age may further moderate the relationships tested in Aim 2. To test the hypothesis that emotional regulation during evocative partner stimuli will be reduced compared to regulation during neutral stimuli (**Hypothesis 2a**), we will test the 2 (evocative vs. neutral) x 2 (WATCH vs. DON'T REACT) interaction term, collapsing across partner type in the placebo condition. To test the hypothesis

that emotion regulation during evocative partner stimuli will be reduced by alcohol, (**Hypothesis 2b**) we will test the 2 (evocative vs. neutral) x 2 (WATCH vs. DON'T REACT) interaction term collapsing across partner type in the alcohol condition. To test the hypothesis that DV partners are less able to regulate emotion during evocative stimuli than the DNV partners (**Hypothesis 2c**), we will test the 2 (DV vs. DNV) x 2 (evocative vs. neutral) x 2 (WATCH vs. DON'T REACT) in the placebo condition. Finally, to test the hypothesis that alcohol interferes with the ability to regulate emotion for DV partners compared to DNV partners (**Hypothesis 2d**), we will test the 2 (DV vs. DNV) x 2 (alcohol vs. placebo) x 2 (evocative vs. neutral) x 2 (WATCH vs. DON'T REACT) interaction.

15) Provisions to Monitor the Data to Ensure the Safety of Subjects

1. The experienced and qualified professionals responsible for determining serious adverse events in the proposed study "Emotions and Decisions of Couples" will be the PI and co-Investigator for the study Brandi Fink, Ph.D. and Eric Claus, Ph.D. Dr. Claus has experience with both oral and intravenous alcohol administration and will work with Dr. Fink to identify any adverse events.

Any serious adverse events that do occur during the course of the study will immediately be reported to the University of New Mexico Human Research Protections Office as an adverse event.

2. Monitoring of the occurrence of adverse events will occur after each study session and one week after the last study session. Monitoring of adverse events will be conducted via a telephone call to each partner the day following a study session and to each partner, again, one week after the completion of all study sessions. The purpose of this monitoring is to ensure that study sessions were not responsible for violent arguments between the partners. Objectivity in assessing adverse events will be ensure by proper training by the PIs and an immediate notification of both PIs if an adverse event has occurred. Additionally, a PI will follow-up with the partners to confirm the details of such an event.

Because this study also involves an alcohol administration procedure, we also have protections surrounding the consumption of alcohol and will be monitoring this for adverse events, as well. First, participants must be weekly drinkers and must have reported at least two binge drinking episodes in the previous month (>4 drinks for males, >3 drinks for females); therefore, the study will not use alcohol-naïve participants, but individuals who routinely reach the level of blood alcohol concentrations that will be obtained during the study procedures. Secondly, the participants must remain in the laboratory until their blood alcohol concentration falls to between .02% - .04%. Note that this level is within the recommended range (.02% - .04%) for safe release of participants based on the NIH National Institute on Alcohol Abuse and Alcoholism (NIAAA) guidelines (http://www.niaaa.nih.gov/Resources/ResearchResources/job22.htm). Also consistent with NIAAA guidelines, release will require two consecutive readings of a BAC of .03% or below. During detoxification participants will be seated in a private room, given refreshments, and the choice of a variety of TV or movie comedies to view while their BAC is descending. Should a participant insist on leaving the lab before their BAC reaches .03%, the researchers will again calmly discuss the reasons for requiring the participant remain in the laboratory (e.g., physical safety of participant, etc.). If this is futile and the participant continues to insist on

leaving, the participant will be allowed to do so. If the participant is attempting to leave via driving his/her own vehicle, the police will be called and notified. This procedure will be disclosed to participants during the informed consent.

3. On a yearly basis, the PIs will file a report to HRRC that contains all adverse events that occurred in the prior year. The study will be terminated should it be determined that study procedures resulted in violent arguments in three or more couples.

4. All female participants will be required to take a urine-based pregnancy test on any day in which they will participate in the experimental conditions (placebo and alcohol). If a participant tests positive for pregnancy, she will not be allowed to continue with the study and will be paid at a prorated rate.

5. The PI and collaborators for the study will always be present or on call while participants are undergoing administration of alcohol.

6. The study will involve administering alcohol to participants, and will be done in accordance with NIAAA guidelines for administering alcohol in human studies (www.niaaa.nih.gov/Resources/ResearchResources/job22.htm). All participants will be 21 years of age or older. Before administration participants will be notified of how much alcohol they will receive in terms of standard drinks and peak blood alcohol range in plain English, and will also be informed about the length of time required to participate in the study and for their blood alcohol levels to return to safe levels (<.03g%). Participants will be instructed not to drive to appointments. Once the experiment is completed, participants will be directed to a private assessment room that is near a bathroom that can be monitored easily by research associates. Participants will also be provided with snacks and water after participating. Before participants will be allowed to leave the CTSC laboratory, two consecutive breath alcohol concentration readings that are .03g% or below will be required. Finally, participants will be compensated with a gift card payment of $40 after the placebo session and $100 after the alcohol session. The alcohol session payments include the time during which the participant is decreasing to .03g%.

7. Referral to treatment: We are excluding participants who meet DSM-IV criteria for alcohol dependence based on an initial phone screen. If participants meet diagnostic criteria for alcohol dependence at the laboratory visit, however, they will be provided with an active referral consisting of a research staff contacting local treatment facilities if the participant so chooses. The study does not have a follow-up phase so we will not monitor increases in alcohol use over time.

8. All data is coded with a unique subject number and only trained study staff will review identifiable data. All data after initial entry into the study is coded based on the unique subject number, which de-identifies the data. Although a master list with links to subject identities will be kept for the duration of the study, this list will be maintained on a separate password protected computer, thus making the risk of identification of a participant very unlikely. Participants' digitized videos will be given a unique subject number and will be maintained on secure serves housed at the CTSC. Digitized videos will be destroyed at the completion of the study unless the couple has (both partners) have granted the Dr. Fink permission to retain the videos for training

of research staff in the SPAFF only. The people who will have access to the data include members of the research team. Identifiable data will not be shared with investigators outside of the research team. The data is also available to the HRRC and other regulatory agencies for audit purposes only.

9. The research proposed is not a Phase III clinical trial, so does not require an independent data and safety monitoring board.

16) Withdrawal of Subjects

The participants may withdraw from the study at any time without it affecting access to referral information. Participants may also request not to participate in the video-taped discussion of a disagreement, or request that the video-recorded discussion of a disagreement be deleted. Participants will be advised, however, that this will result in them being excluded from the remaining sessions of the study. Also, if a participant decides to discontinue his or her participation after they have consumed alcohol, he or she will be required to remain in the laboratory until their blood alcohol concentration (BAC) falls to .03 or below. If a participant insists on leaving before his/her BAC falls to at least .03, and he/she is in own vehicle, study staff will be required to notify the authorities. Participants will be informed of this stipulation during the informed consent process.

The investigators have the right to end any participant's participation in this study if it is determined that the participant no longer qualifies to take part, does not follow study procedures, or if it is in best interest of the participant, that of the participant's partner, or the study's best interest to stop your participation. The Principal Investigators may stop the study at any time.

17) Risks to Subjects

Risks Associated with Study Participation:

1. There is an uncommon risk of boredom or intrusiveness pertaining to the completion of measures pertaining to the couples' relationship functioning and drinking.

2. There is a common risk of some participants becoming slightly intoxicated that may lead to temporary impairment in motor coordination as a result of consuming alcohol.

3. There is a common risk of discomfort to participants in discussing an area of ongoing disagreement with their partner.

4. There is a rare, but serious risk of partner violence occurring after participating in the discussion of an area of disagreement and after viewing task stimuli in subsequent visits.

5. There is also a rare, but serious risk of a loss of confidentiality and privacy that includes the identification of participants by their video image, an invasion of privacy, social and economic risks, alterations in relationships with others that are to the disadvantage of the participant,

embarrassment, loss of respect of others, labeling with negative consequences or diminishing the participant's opportunities and status in relation to others.

6. There is also the risk of unanticipated risks.

Protection Against Risks Associated with Study Participation:
1. To protect against the risk of boredom or intrusiveness, we will provide breaks to the participants during the completion of study measures. The interviewers are also trained in discussing sensitive material with clinical research participants. If a participant finds a topic uncomfortable, they will be able to skip those questions or discontinue their participation.

2. To protect against the risk of adverse outcomes for participants as a result of consuming alcohol, participants may discontinue their participation at any time, however, they will not be allowed to leave until after their BAC is below .03, consistent with NIH/NIAAA guidelines. In addition, because we are recruiting couples in which both partners consume alcohol, alcohol will not be administered to alcohol naïve participants as this would entail and unknown level of risk. Participants will also be provided with a detailed list of substance abuse providers and research staff will assist in arranging an appointment with the participant's top choice of treatment facility, if desired by the participant.

3. and 4. To protect against the aforementioned risk of discomfort resulting from the discussion of disagreement and the risk of partner violence as a result of the experimental procedure, we will follow to procedures described by Gottman et al., 1995, except we will extend the procedures to the males in our pilot study. Both partners will separately complete an adjective checklist at the conclusion of each laboratory visit to assess the dangerousness of the situation. If any partner indicates he or she is feeling any negative emotion other than "feeling somewhat negative" the partner will be interviewed separately and the PI, a clinical psychologist with over eight years of working with violent couples, will use interviewing techniques to soothe the partner. UNM Campus Police will be informed of the study and will be on call within two minutes of the laboratory in the event they are needed. All participants (male and female) will also be given referrals to shelters, resources for obtaining legal representation and instructions on filing for orders of protection. Lastly, we will call each participant the night after each study procedure and one week after the last study visit to ensure that our study procedures did not lead to violent arguments. A violent argument is any argument resulting from participation in the study that leads to the use of physical aggression between partners, to include throwing or hitting the partner with an object.

5. To protect against the risk of loss of confidentiality and privacy, study recruitment materials will not identify the study as being one involving partner violence. Study recruitment materials (see attached) will recruit for couples in unhappy relationships who drink at least weekly. In additon, to protect against a breach of confidenitality of study materials, including the viewing of incorrect partner stimuli, all couples will be given a numerical code unique to each couple and that indicates the partner (e.g., participant 100-01, 100-02 = couple 100, partner 01 and partner 02). Furthermore, all collected measures will be identified only by numeric code and stored in locked filing cabinets in locked data storage rooms at the UNM CTSC. Video images will be immediately labeled with the couple and participant numerical code. The video images will be

encrypted and saved on secure and HIPAA compliant servers through the UNM HSC Department of Psychiatry and Behavioral Sciences. Furthermore, to prevent inadvertent presentation of partner stimuli to the wrong partner of a couple, research assistants will be required to sign off on a "Participant Stimuli Verification Form" that he or she has viewed the experimental program and has verified that the correct stimuli is being presented to the correct partner. A second research assistant will also view the experimental program, and counter-sign the form ensuring that stimuli is correct. The list linking the numerical ID code to the participant's identifying information will be maintained separately from study material.

18) Potential Benefits to Subjects

The possible direct benefits to participants from participating in the study is referral to resources which may be helpful to them in ending violence in their relationships. The benefits to society are much greater, however. Currently there are NO EFFECTIVE INTERVENTIONS for partner violence (Babcock, Green & Robie, 2004). This is largely because current treatments target behavior that has been socially determined, not scientifically determined. This study is one in a series that will identify targets of intervention for partner violence which will be the first step in the development of effective interventions for partner violence.

19) Vulnerable Populations

N/A

20) Multi-Site Research

N/A. All work will be conducted at UNM Health Science Center.

21) Community-Based Participatory Research/Field Research

N/A. Research is experimental and will be conducted in Dr. Fink's laboratory housed in the CTSC.

22) Sharing of Results with Subjects/Incidental Findings

At this time, our behavioral study procedures do not lend themselves to the discovery of incidental findings. At the conclusion of the study procedures, all participants will be informed of the study hypotheses.

23) Resources Available

Drs. Fink and Claus, as well as their collaborators have conducted studies that use overlapping methodology with the current study, including the measurement of psychophysiological responses (i.e. pupillometry, skin conductance and heart rate variability), and measurement of acute alcohol effects on executive control. First, Dr. Fink has published couples research examining the effects of intraindividual responses to relationship distress and their effects on depressive symptoms. She has also published behavioral methods for improving adaptive behavioral displays of couples in therapy sessions that improve generalization and utilization of new skills outside of therapy. In addition, Dr. Fink has published studies in which skin conductance response, and heart rate variability were the dependent variables. Dr. Claus has conducted both oral and

intravenous route alcohol administration studies to examine how individual differences in alcohol induced impairment relates to subjective measures of sensitivity to the effects of alcohol (R21-AA020304). Dr. Hamilton has published pupillometry data during task performance, and has shown differences in pupil diameter in response to individually salient stimuli. As seen in Figure 2, pupil diameter was increased, an indication of increased arousal, during the recognition of the salient stimuli. Finally, Dr. Cavanagh has published research using nearly all common techniques associated with human autonomic system functioning, and has applied them to assessments of cognitive and affective control.

In addition, Dr. Fink is a Clinical Psychologist with extensive training and experience in psychological assessment, and the conduct of prospective, longitudinal, substance use disorders treatment outcome and program evaluation studies. She also has received additional training in advanced statistical methods such as, dyadic data analysis techniques, Multi-Level Modeling and Structural Equation Modeling and am also trained in the Facial Action Coding System (FACS) and Specific Affect Coding System (SPAFF) for the coding of dyadic behavior. Dr. Fink's most recent training as a postdoctoral fellow on an NIAAA Institutional Research Training Grant provided me with additional training and expertise to study on the effects of alcohol on the dyadic behavior of couples. Dr. Fink also has experience developing and conducting treatment protocols including the Family Assessment and Intervention Research (FAIR), partner violence treatment program for the Second Judicial District Court in Albuquerque, NM and a substance abuse treatment program for recipients of Temporary Aid for Needy Families (TANF), currently being piloted in Bernalillo County, New Mexico.

Equipment: The UNM Clinical and Translational Science Center houses Dr. Fink's laboratory and contains updated equipment and IT capabilities including high-speed IT links to collaborating institutions such as the Mind Research Network (MRN), imaging and data analysis, neuropsychological testing rooms, a server room, and secure data storage. The UNM Clinical and Translational Science Center has furnished Dr. Fink's laboratory will all necessary software and equipment for conducting her program of research including furniture, computers, electroencephalography (EEG), psychophysiological and eye-tracking equipment. EEG and psychophysiological data will be collected using the BrainVision actiCHamp 64-channe, DC amplifier, 24-bit biopotential system. Skin conductance, respiration, heart rate and heart rate variability will be collected using the BrainVision GSR module, respiration belt and EKG leads, respectively. Pupillary response will be collected using the Eyelink 100 Plus high speed camera system by SR Research.

Please see attached CTSC Resources Attachment for further resource explanation.

24) Prior Approvals/Attachments Requiring Signatures

The current application is a protocol modification of an existing approved protocol (HRPO #12-433) and does not require prior approval from other entities.

25) Confidentiality

Please refer to Section 14 (Data Management) and Section 17 (Protection Against Risk for Participation) for the procedures for maintaining confidentiality.

In addition, we have obtained a Certificate of Confidentiality from the Department of Health and Human Services via the National Institute on Alcohol Abuse and Alcoholism.Because this is a study involving couples, NIAAA was concerned that if one partner revealed study participation in a court setting that the CoC would no longer be in effect and would not be able to protect participants from forced release of study participation. Per the request of NIAAA, we have worked with the UNM Legal Counsel to amend the consent form to include a statement indicating that "Your signature below also indicates that you understand that The University of New Mexico will not release, under any circumstances, any raw data including videos to participants."

26) Provisions to Protect the Privacy of Subjects

Recruitment: To protect against the risk of loss of confidentiality and privacy, study recruitment materials will not identify the study as being one involving partner violence. Study recruitment materials (see attached) will recruit for couples in unhappy relationships who drink at least weekly.

Consent: As described above, each partner will be participate in an informed consent procedure in a private interview room or Dr. Fink's laboratory in the CTSC to ensure that "eavesdropping" or observation by non-study team members is not possible. An additional protection to protect the privacy of study participants is that all participants will be greated by only a research assistant in the lobby of the CTSC and escorted to the laboratory.

Data Collection: Data collection will occur in a private interview room or Dr. Fink's laboratory in the CTSC. Only trained members of the research team are permitted access to any participant data.

27) Compensation for Research-Related Injury

In the consent form, participants will be informed that UNM HSC will provide emergency treatment at their cost and that no commitment is made by UNM HSC to provide free medical care or money for injuries from participating in this study. Participants will also be informed in the consent form that in the event that they have an injury or illness that is caused by their participation in this study, reimbursement for all related costs of care will be sought from their insurer, managed care plan, or other benefits program. If they do not have insurance, they will be informed that they may be responsible for these costs. Participants will also be responsible for any associated co-payments or deductibles required by their insurance.

Economic Burden to Subjects

N/A.

- List any costs to participants (or their 3rd party payer); include any charges for study procedures, visits, or drug/devices.
  Ensure that the cost section of the consent form reflects the costs that are covered by the sponsor and the costs for which the participant (or 3rd party payer) are responsible.

Research Procedures	Number of Samples/Procedures	Responsible Party	
		Study	3rd Party Payer or Participant
_____	_____		
_____	_____		
_____	_____		
_____	_____		
_____	_____		
_____	_____		
_____	_____		
_____	_____		
Standard of Care Procedures	**Number of Samples/Procedures**	**Responsible Party**	
		Study	**3rd Party Payer or Participant**
_____	_____		
_____	_____		
_____	_____		
_____	_____		
_____	_____		
_____	_____		
_____	_____		
_____	_____		

28) Consent Process (including waiver request for HIPAA, waiver of HIPAA for recruitment only, Waiver of Informed Consent, and Alteration of Informed Consent)

Consent

The PI, co-investigator or other research associate will be responsible for obtaining informed consent. The consenting process process will be conducted for each partner separately and in separate rooms in Dr. Fink's laboratory and in an additional interview room in the CTSC. The language used in the consent form will be easy to understand, participants will be reminded that they are free to not participate, or discontinue participation at any time during the study. If, however, it is during the alcohol adminsitration condition the participant must wait until their BAC is .03 or lower and participants must be not be displaying any angry affect greater than "feeling somewhat negative" prior to leaving the research site. Participants will also be informed that they are free to withdraw any information provided during the study, including erasing portions of the video recording. Should a participant make this request, it would result in the exclusion of the couple from further procedures and participation in the study as their video-recorded communication discussion will be used at stimuli in subsequent study phases.

Waiver or Alteration of Informed Consent: ***Review the "CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)"in the Click IRB Library to ensure you have provided sufficient information for the HRRC to make these determinations.***

(0.05)

N/A

Waiver of Written Documentation of Consent: ***Review the "CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)" in the Click IRB library to ensure you have provided sufficient information for the IRB to make these determinations.***

N/A

HIPAA Authorization

The identifiers collected during the course of this study will be participant name, and a contact phone number for scheduling participant study sessions. Digital video images of participants will also be collected. The PHI collected in this study includes participant questionnaire answers, neurophysiological responding and computer task responses.

Waiver of HIPAA authorization: ***Review the "CHECKLIST: HIPAA Waiver of Authorization (HRP-441)" in the Click IRB library to ensure you have provided sufficient information for the IRB to make these determinations.***

N/A

Non-English Speaking Subjects

N/A

Planned Emergency Research Consents

N/A

Cognitively Impaired Adults/ Adults Unable to Consent/ Use of a Legally Authorized Representative (LAR)

N/A

29) Drugs or Devices

No experimental drugs or devices are used in this study. All devices have been approved for the collection of research data. EEG and psychophysiological data will be collected using the BrainVision actiCHamp 64-channe, DC amplifier, 24-bit biopotential system. Skin conductance, respiration, heart rate and heart rate variability will be collected using the BrainVision GSR module, respiration belt and EKG leads, respectively. Pupillary response will be collected using the Eyelink 100 Plus high speed camera system by SR Research. All equipment is approved for research data collection.

Drugs: Please respond to all questions in this section and include a completed and signed Drug Attachment form.

N/A. No experimental drugs are being used in this study.

Medical Devices: Please respond to all questions in this section.

N/A. There are no experimental medical devices being used in this study. The equipment being used is approved for experimental research use.

Humanitarian Use Device (HUD):

N/A.

Remember to save the completed protocol as a Word document so that if changes are required, you can submit them as track changes with a new version number and/or version date.
Please review the IRB Submission Checklist in the IRB Library to ensure you have all required documents for your IRB submission.

The University of New Mexico
Consent to Participate in Research

The Emotions and Decisions of Couples

June 13, 2018

Purpose and General Information

You are being asked to participate in a research study that is being done by Brandi C. Fink, Ph.D., who is the Principal Investigator, Eric D. Claus, Ph.D., of the Mind Research Network. This research is being done to evaluate the role of alcohol in the emotions and decisions you make when in conflict with your partner. You are being asked to participate because you said you are in a long-term relationship, you drink alcohol, and you have severe relationship conflict. Approximately 224 couples will take part in this study at the University of New Mexico.

This form will explain the study to you, including the possible risks as well as the possible benefits of participating. This is so you can make an informed choice about whether or not to participate in this study. Please read this Consent Form carefully. Ask the investigators or study staff to explain any words or information that you do not clearly understand.

What will happen if I participate?

If you agree to be in this study, you will be asked to read and sign this Consent Form. After you sign the Consent Form, the following things will happen:

1. You and your partner will complete several questionnaires asking you about various aspects of your relationship and the alcohol that you drink.

2. You will then participate in an interview with the researcher about areas of disagreement in your relationship. With the researcher you will choose one or two areas of disagreement to talk about with your partner while this discussion is video-recorded. We call this the "couple's session."

3. After you complete the couple's session, you or your partner will be asked to return to the laboratory two more times. We call these the "individual sessions." If you are the person chosen to participate in the individual sessions, the following things will happen: We will remind you to please not use any drugs or alcohol for 24 hours prior to your individual sessions. You will be given a breathalyzer at the beginning of each session. During each of these individual sessions, you will either drink an alcoholic beverage or a nonalcoholic beverage after which you will complete several computer tasks.

    a. During the alcohol session you will be asked to consume a mixture of alcohol and juice at a dose that is intended to achieve a maximum target breath alcohol concentration (BAC) of up to .08mg%. The volume of beverages will depend on your body weight, age and height. You will be

asked to consume the beverage given to you within 9 minutes and then wait until your BAC reaches a pre-determined target BAC level.

b. If you are female, we will ask you to take a pregnancy test before each individual session.
c. One computer task involves watching a computer screen change colors, another computer task involves you viewing video clips of your partner from your previous couple's session discussion of a disagreement, and another computer task that involves you making decisions based on the instructions you receive.

d. During these computer tasks, we will also be using electrodes to collect various measures from you like brain waves, heart rate, pulse, breathing rate and how much your skin perspires.

e. If you drank alcohol during one or both of the individual sessions, you will be required to remain in the laboratory after the experiment until your blood alcohol concentration (BAC) falls to .03. We will provide you with movies or TV programs to watch while we are waiting for this to happen.

f. If you did not drive yourself to the session, you will also be required to have a friend or relative (not your partner) pick you up from the individual sessions. This is to make sure you are safe after consuming alcohol.

4. Also, research staff will telephone you the day after your couple's, the day after the individual study sessions, and one week after the last study visit to ensure that you remain safe.

Participation in this study will take a total of eight (8) hours over a period of three (3) days. The first couples session will take approximately two (2) hours, and depending on the type of beverage that you consume in the individual sessions, the individual sessions may take up to five (5) hours. We ask that you allow five (5) hours for the completion of the individual sessions.

What are the possible risks or discomforts of being in this study?
Every effort will be made to protect the information you give us. There is, however, an uncommon risk of boredom or intrusiveness due answering questions about your relationship and drinking. There is a common risk of some participants becoming slightly intoxicated that may lead to temporary impairment in motor coordination as a result of consuming alcohol. There is also a common risk of discomfort to participants in discussing an area of ongoing disagreement with their partner. There is a rare, but serious risk of partner violence occurring after participating in the discussion of an area of disagreement, after viewing task stimuli in subsequent visits, and after consuming alcohol. There is also a rare, but serious risk of a loss of confidentiality and privacy that includes the identification of participants by their video image, an invasion of privacy, social and economic risks, alterations in relationships with others that are to the disadvantage of the participant, embarrassment, loss of respect of others, labeling with negative consequences or diminishing the participant's opportunities and status in relation to others. There may also be risks that we cannot anticipate.

How will my information be kept confidential?

Your name and other identifying information will maintained in locked files in a locked office at UNM and secure servers at the UNM Health Sciences Center, available only to the authorized members of this research team for the duration of the study. For any information entered into a computer, the only identifier will be a unique study identification (ID) number. Any identifying information and any record linking that information to the study ID numbers will be destroyed when the study is completed, approximately two years from now. Information resulting from this study will be used for research purposes and may be published; however, you will not be identified by name in any published reports about this study.

No one other than this study's research staff will have access to your video-recorded discussions of a disagreement. Because research study's often take years to complete, analyze and interpret the results, by signing this Consent Document you agree to the uses of your data indefinitely. We would also like permission to use your video-recordings in training other research staff in our research team. The video-recordings will not be used to train staff outside of our research team. If you give us permission and change your mind later, please contact Dr. Fink in writing at the address below and your video-recordings will no longer be used for training. Please be advised that your partner must also agree to the video-recordings being used in training research staff in order for us to use them. If your partner does not want his or her video-recording to be used, we will not use your video-recording either.

_____ Yes, I agree to allow my videos to be used for training purposes. I understand that individuals being trained to use these interviews will be able to see my face. _____ (participant initials)

_____ No, I do not agree to allow my videos to be used for training purposes. _____ (participant initials)

We would also like to ask your permission to contact you to participate in future research. By initially below and providing your preferred method of contact (e.g., email, phone, etc.), you will allow a trained research staff member to contact you in the future to ask if you want to participate in any studies. You have no obligation to participate in any future study. Declining to initial below or provide contact information does not affect your participation in the current study and there will be no penalty or loss of benefits to which you are entitled as part of the current research study. Your contact information will not be shared with anyone outside of this research team and you may withdraw your permission at any time by contacting Dr. Fink at the address below.

_____ Yes, I agree to allow the research staff to contact me about participating in future studies. _____ (participant initials)

Preferred contact method: Phone: _____

Mail: _____

Email address: _____

_____ No, I do not wish to be contacted about participating in future studies. _____ (participant initials)

Information from your participation in this study may be reviewed by the federal and state regulatory agencies, and by the UNMHSC Human Research Review Committee (HRRC) which provides regulatory and ethical oversight of human research. There may be times where we are required to share your information. Your name will not be used in any published reports about this study. If, however, we feel that you or someone else is in imminent danger or if we learn of a child in danger we will notify the appropriate authorities.

What are the benefits to being in this study?
There may be no direct benefit to you from being in this study. Your participation may help find out information about couples with severe relationship conflict that will lead to better treatments for them. You will also receive referral information that may be helpful in stopping the severe conflict in your relationship.

What other choices do I have if I don't participate?
Taking part in this study is voluntary so you can choose not to participate. Refusal to participate in this study will not involve any penalty to you or loss of benefits to which you are otherwise entitled to receive.

Will I be paid for taking part in this study?
Each partner will be paid $20 per hour for his/her participation for a total of $200 per couple. You will be paid with a cash gift card at the conclusion of each study session in which you participate.

What will happen if I am injured or become sick because I took part in this study?
If you are injured or become sick as a result of this study, University of New Mexico Health Sciences Center (UNM HSC) will provide you with emergency treatment at your cost.

No commitment is made by the University of New Mexico Health Sciences Center (UNMHSC) to provide free medical care or money for injuries to participants in this study.

In the event that you have an injury or illness that is caused by your participation in this study, reimbursement for all related costs of care will be sought from your insurer, managed care plan, or other benefits program. If you do not have insurance, you may be responsible for these costs. You will also be responsible for any associated co-payments or deductibles required by your insurance.

It is important for you to tell the investigator immediately if you have been injured or become sick because of taking part in this study. If you have any questions about these issues, or believe that you have been treated carelessly in the study, please contact the UNMHSC Human Research Review Committee (HRRC) at (505) 272-1129 for more information.

Can I stop the study once I begin?
Yes. You can withdraw from this study at any time without affecting your access to referral information. You can also request not to participate in the video-recorded session or request that your video-recording be deleted. Please be advised, however, that this will result in you and your partner being excluded from the

remaining sessions of the study. Also, if you decide to discontinue your participation after you have consumed alcohol, you will be required to remain in the laboratory until your blood alcohol concentration (BAC) falls to .03mg% or below. You will still be required to have a friend or relative (other than your partner) pick you up from the session. If you insist on leaving before your BAC falls to at least .03mg%, we will be required to notify the authorities.

The investigators have the right to end your participation in this study if they determine that you no longer qualify to take part, you do not follow study procedures, or if it is in your best interest, that of your partner, or the study's best interest to stop your participation. The Principal Investigator may stop the study at any time. Participants will be informed of any new findings during the course of the study that may influence their decision to participate.

Certificate of Confidentiality

We will do everything we can to keep others from learning about your participation in this study. To further help us protect your privacy, we have obtained a Certificate of Confidentiality from the United States Department of Health and Human Services (DHHS).

With this Certificate, we cannot be forced (for example by court order or subpoena) to disclose information that may identify you in any federal, state, local, civil, criminal, legislative, administrative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except to prevent serious harm to you or others, and as explained below.

You should understand that a Certificate of Confidentiality does not prevent you, or a member of your family, from voluntarily releasing information about yourself, or your involvement in this study.

If an insurer or employer learns about your participation, and obtains your consent to receive research information, then we may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy.

Again, and as mentioned above, you should understand that we will in all cases, take the necessary action, including reporting to authorities, to prevent serious harm to yourself, children, elderly persons or others. For example, in the case of child abuse or neglect.

A Certificate of Confidentiality does not represent an endorsement of the research study by the Department of Health and Human Services or the National Institutes of Health.

Refusal to Sign

If you choose not to sign this Consent Document and authorization for the use of your health information, you will not be allowed to take part in the research study.

What if I have questions or complaints about this study?

If you have any questions, concerns or complaints at any time about the research study, Brandi C. Fink, Ph.D., or her associates will be glad to answer them at (505) 272-6045, Monday through Friday, 9:00a.m. to 5:00p.m. If you would like to speak to someone other than the research team, you may call the UNM HRRC office at (505) 272-1129. The HRRC is a group of people from UNM and the community who provide independent oversight of safety and ethical issues related to research involving human participants.

What are my rights as a research participant?

If you have questions regarding your rights as a research participant, you may call the Human Research Protections Office (HRPO) at (505) 272-1129 or visit the HRPO website at http://hsc.unm.edu/som/research/hrrc/.

Consent and Authorization

You are making a decision whether to participate in this study. Your signature below indicates that you read the information provided (or the information was read to you). Once again, you should understand that we will in all cases, take the necessary action, including reporting to authorities, to prevent serious harm to yourself, children, elderly persons or others, as in the case of child abuse. Your signature below also indicates that you understand that The University of New Mexico will not release, under any circumstances, any raw data including videos to participants. By signing this Consent Document, you are not waiving any of your legal rights as a research participant.

I have had the opportunity to ask questions and all questions have been answered to my satisfaction. By signing this Consent Document, I agree to participate in this study and give permission for my health information to be used or disclosed as described in this Consent Document. A copy of this Consent Document will be provided to me.

_____ _____/_____

Name of Adult Participant (print) Signature of Adult Participant Date

I have explained the research to the participant and answered all of his/her questions. I believe that he/she understands the information in this Consent Document and freely consents to participate.

_____ _____/_____

Name of Research Team Member (print) Signature of Research Team Member Date